

IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF MASSACHUSETTS  
EASTERN DIVISION

Mary Mullaney, )  
                    Plaintiff, )  
                    )  
v.                 ) CIVIL ACTION  
                    Wyeth, Inc.; Wyeth Pharmaceuticals, Inc.; Wyeth-Ayerst ) NO. 04-11375 GAO  
International, Inc.; and Interneuron Pharmaceuticals, Inc., )  
                    )  
                    Defendants. )  
                    )  
                    )

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**ANSWER OF DEFENDANTS WYETH, INC.,**  
**WYETH PHARMACEUTICALS INC. AND WYETH-AYERST INTERNATIONAL,**  
**INC. TO PLAINTIFF'S COMPLAINT**

Defendants Wyeth, Inc.,<sup>1</sup> Wyeth Pharmaceuticals Inc.<sup>2</sup> and Wyeth-Ayerst International, Inc. ("hereinafter collectively referred to as "Answering Defendants") answer the enumerated paragraphs of plaintiff's Complaint as follows:

**INTRODUCTION**

1. To the extent that paragraph 1 of the Complaint contains factual allegations about the general public that in no way pertain to plaintiff, no response from Answering Defendants is required. Answering Defendants admit that, prior to September 15, 1997, Robins manufactured

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<sup>1</sup> On August 3, 1998, A.H. Robins Company Inc. ("Robins") was merged into American Home Products Corporation ("AHPC") and ceased to exist as a separate entity. On March 11, 2002, the name of AHPC changed to Wyeth. On March 11, 2002, AHPC's unincorporated division, Wyeth Ayerst Laboratories Division ("WALD") changed its name to Wyeth Pharmaceuticals ("WP"). Because WP is an unincorporated division of Wyeth, Wyeth will respond to allegations directed at WP.

<sup>2</sup> On January 1, 1999, Wyeth Laboratories Inc. ("WLI") was merged into Ayerst Laboratories Inc. The surviving company was Ayerst Laboratories Inc., the name of which was changed to Wyeth-Ayerst Pharmaceuticals Inc ("WAPI"). On March 22, 2002, the name of Wyeth-Ayerst Pharmaceuticals Inc ("WAPI") changed to Wyeth Pharmaceuticals Inc. ("WPI").

Pondimin® brand of fenfluramine hydrochloride ("Pondimin") which was sold in interstate commerce. Answering Defendants admit that prior to September 15, 1997, AHPC, through WALD, distributed and sold Pondimin in interstate commerce for use in accordance with its FDA-approved prescribing information and subject to the precautions, warning and contraindications stated therein. Answering Defendants admit that, prior to September 15, 1997, AHPC, through WALD, distributed, promoted to licensed health care providers, and sold Redux™ brand of dexfenfluramine hydrochloride ("Redux") in interstate commerce for use in accordance with its FDA-approved prescribing information and subject to the precautions, warnings and contraindications stated therein. Answering Defendants admit that prior to September 15, 1997, WLI distributed Pondimin and Redux. Answering Defendants further admit that prior to September 15, 1997, Wyeth-Ayerst Laboratories Company ("WALCo.") promoted Redux to licensed health care providers and sold Redux for use in accordance with its FDA-approved prescribing information and subject to the precautions, warnings and contraindications stated therein. Answering Defendants admit that Pondimin and Redux were voluntarily withdrawn from the market on September 15, 1997. Answering Defendants deny each and every other allegation of paragraph 1 of the Complaint.

2. Paragraph 2 of the Complaint is characterization of the Complaint and the relief sought thereby. Answering Defendants admit that plaintiff so characterized her Complaint, but deny the characterization. Answering Defendants are without information sufficient to form a belief as to the truth of the allegations pertaining to the plaintiff and, therefore, deny same. Answering Defendants incorporate the response to paragraph 1 except for the first and last sentences. Answering Defendants deny the remaining allegations of paragraph 2 of the Complaint.

3. Answering Defendants deny the allegations of paragraph 3 of the Complaint.
4. Answering Defendants are without information sufficient to form a belief as to the truth of the allegations of paragraph 3 and, therefore, deny them.
5. Answering Defendants say that the allegations of paragraph 5 are a conclusion of law that requires no response. To the extent a response may be required, Answering Defendants deny the allegations of paragraph 5.
6. Paragraph 6 of the Complaint is a statement of definition to which no response is required.
7. Answering Defendants deny each and every allegation of paragraph 7 of the Complaint.
8. Answering Defendants deny each and every allegation of paragraph 8 of the Complaint.
9. Answering Defendants admit that, prior to September 15, 1997, Robins manufactured, labeled and packaged Pondimin which was sold in interstate commerce. Answering Defendants admit that prior to September 15, 1997, AHPC, through WALD, labeled, marketed, distributed and sold Pondimin in interstate commerce for use in accordance with its FDA-approved prescribing information and subject to the precautions, warnings and contraindications stated therein. Answering Defendants admit that, prior to September 15, 1997, AHPC, through WALD, labeled, marketed, distributed, promoted to licensed health care providers and sold Redux in interstate commerce for use in accordance with its FDA-approved prescribing information and subject to the precautions, warnings and contraindication stated therein. Answering Defendants admit that prior to September 15, 1997, WLI distributed Pondimin and Redux. Answering Defendants further admit that prior to September 15, 1997,

WALCo promoted Redux to licensed health care providers and sold Redux. Answering Defendants deny each and every other allegation of paragraph 9 of the Complaint.

10. Answering Defendants admit that prior to September 15, 1997, AHPC, through WALD, distributed and sold Pondimin and Redux in interstate commerce for use in accordance with its FDA-approved prescribing information and subject to the precautions, warnings and contraindications stated therein. Answering Defendants deny each and every other allegation of paragraph 10 of the Complaint.

11. Answering Defendants deny each and every allegation of paragraph 11 of the Complaint.

12. Answering Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 12 of the Complaint concerning plaintiff's use of Pondimin and/or Redux and residence and, therefore, deny same. Answering Defendants deny each and every other allegation of paragraph 12 of the Complaint.

13. Answering Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 13 and, therefore, deny same.

14. Answering Defendants admit that, prior to September 15, 1997, Robins manufactured Pondimin which was sold in interstate commerce. Answering Defendants admit that prior to September 15, 1997, AHPC, through WALD, marketed, distributed, and sold Pondimin in interstate commerce for use in accordance with its FDA-approved prescribing information and subject to the precautions, warnings and contraindications stated therein. Answering Defendants admit that, prior to September 15, 1997, WLI distributed Pondimin. Answering Defendants say that the last sentence of paragraph 14 is a conclusion of law that requires no response. To the extent a response is required, said sentence is denied. Answering

Defendants admit that Wyeth is incorporated under the laws of the state of Delaware with a principal place of business in New Jersey. Answering Defendants deny all other allegations in paragraph 14.

#### **The Pharmaceutical Company Defendants**

15. Answering Defendants admit that Wyeth Pharmaceuticals was formerly known as WALD, is an unincorporated division of Wyeth, and is not separately amenable to suit. Answering Defendants further admit that from approximately December, 1989 to September 15, 1997, AHPC, through WALD, labeled, marketed, distributed, and sold Pondimin, in interstate commerce, including in the Commonwealth of Massachusetts, for use in accordance with FDA-approved prescribing information and all warnings, precautions and contraindications stated therein. Answering Defendants further admit that from June 1996 to September 15, 1997, AHPC, through WALD, labeled, marketed, distributed, promoted, licensed to health care providers and sold, Redux, in interstate commerce, including in the Commonwealth of Massachusetts, for use in accordance with FDA-approved prescribing information and all warnings, precautions and contraindications stated therein. Answering Defendants say the last sentence of paragraph 15 is a conclusion of law requiring no response. To the extent a response is required, it is denied. Answering Defendants deny all other allegations of paragraph 15.

16. Answering Defendants admit that Wyeth-Ayerst International, Inc. is a New York corporation and maintains its principal place of business in New Jersey. Answering Defendants deny the remaining allegations in paragraph 16 of the Complaint.

17. Defendant, Indevus Pharmaceuticals, Inc., f/k/a Interneuron Pharmaceuticals, Inc., ("Interneuron") has its principal place of business at the Ledgemark Center, 99 Hayden Avenue, Lexington, Massachusetts and is incorporated in the State of Delaware. Answering

Defendants are without information sufficient to form a belief as to the truth of the remaining allegations of paragraph 17 and, therefore, deny same.

## II.

### **FACTUAL ALLEGATIONS**

18. Answering Defendants admit that prior to September 15, 1997, WALCo sold Redux. Answering Defendants admit that prior to September 15, 1997, WLI distributed Pondimin and Redux. Answering Defendants deny each and every other allegation of paragraph 18 of the Complaint. With respect to Defendant Indevus, Answering Defendants are without information sufficient to form a belief as to the truth of the allegations and, therefore, deny same.

19. In response to the allegations of paragraph 19 of the Complaint, Answering Defendants assert that Pondimin and Redux are brand names for fenfluramine and dexfenfluramine, respectively. Answering Defendants admit that prior to September 15, 1997, AHPC, through WALD, marketed Pondimin and Redux for use in accordance with their FDA-approved prescribing information and subject to the precautions, warnings and contraindications stated therein. Answering Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations concerning the physicians. Answering Defendants deny each and every other allegation of paragraph 19 of the Complaint.

20. Answering Defendants admit that Pondimin and Redux affect brain serotonin levels. Answering Defendants deny each and every other allegation of paragraph 20 of the Complaint.

21. Answering Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 21 of the Complaint.

22. Answering Defendants admit that fenfluramine and dexfenfluramine affect brain serotonin levels. Answering Defendants admit that dexfenfluramine is the d-isomer of fenfluramine. Answering Defendants deny each and every other allegation of paragraph 22 of the Complaint.

23. Answering Defendants deny the allegations of paragraph 23. As to Indevus, Answering Defendants are without information sufficient to form a belief and, therefore, deny same.

24. Answering Defendants admit that fenfluramine is an anorectic drug and that fenfluramine prescribed in combination with phentermine has been referred to as "fen/phen." Answering Defendants deny each and every other allegation of paragraph 24 of the Complaint.

25. Answering Defendants admit that numerous prescriptions for Pondimin and Redux were written by physicians. Answering Defendants deny each and every other allegation of paragraph 25 of the Complaint.

26. Answering Defendants deny each and every allegation of paragraph 26 of the Complaint.

27. Answering Defendants admit that Robins sponsored an IND/NDA with the FDA in connection with the approval of Pondimin. Answering Defendants deny each and every other allegation of paragraph 27 of the Complaint. With respect to Indevus, Answering Defendants are without knowledge sufficient to form a belief as to the truth of the allegations and, therefore, deny same.

28. To the extent these allegations are based on writings, Answering Defendants state that the writings speak for themselves and any attempt to characterize them is denied. Answering Defendants deny each and every other allegation of paragraph 28 of the Complaint.

29. Answering Defendants state that the writings referenced in paragraph 29 of the Complaint speak for themselves and any attempt to characterize them is denied. Answering Defendants deny each and every other allegation of paragraph 29 of the Complaint. With respect to Indevus, Answering Defendants are without knowledge sufficient to form a belief as to the truth of the allegations and, therefore, deny same.

30. Answering Defendants deny each and every allegation of paragraph 30 of the Complaint. With respect to Indevus, Answering Defendants are without knowledge sufficient to form a belief as to the truth of the allegations and, therefore, deny same.

31. Answering Defendants admit that prior to September 15, 1997, AHPC, through WALD, marketed Pondimin and Redux for use in accordance with their FDA-approved prescribing information and subject to the precautions, warnings and contraindications stated therein. Answering Defendants deny each and every other allegation of paragraph 31 of the Complaint. With respect to Indevus, Answering Defendants are without knowledge sufficient to form a belief as to the truth of the allegations and, therefore, deny same.

32. Answering Defendants deny each and every allegation of paragraph 32 of the Complaint.

33. Answering Defendants deny each and every allegation of paragraph 33 of the Complaint. With respect to Indevus, Answering Defendants are without knowledge sufficient to form a belief as to the truth of the allegations and, therefore, deny same.

34. Answering Defendants deny each and every allegation of paragraph 34 of the Complaint. With respect to Indevus, Answering Defendants are without knowledge sufficient to form a belief as to the truth of the allegations and, therefore, deny same.

35. Answering Defendants admit that numerous prescriptions for Pondimin and Redux were written by physicians. Answering Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations concerning phentermine. Answering Defendants deny each and every other allegation of paragraph 35 of the Complaint. With respect to Indevus, Answering Defendants are without knowledge sufficient to form a belief as to the truth of the allegations and, therefore, deny same.

36. Answering Defendants state that the writings referenced in paragraph 36 of the Complaint speak for themselves and any attempt to characterize them is denied. Answering Defendants deny each and every other allegation of paragraph 36 of the Complaint.

37. Answering Defendants admit that in late 1994, American Cyanamid Company (“Cyanamid”) entered into a “Patent and Know-How Sublicense and Supply Agreement” with Interneuron Pharmaceuticals, Inc. and that prior to that time, Interneuron had entered into a sublicense and supply agreement with Les Laboratoires Servier (“Servier”). Answering Defendants admit, on information and belief, that Cyanamid obtained a sublicense from Interneuron with respect to dexfenfluramine and the “Patent and Know-How Sublicense and Supply Agreement” between Cyanamid and Interneuron was with respect to dexfenfluramine. Answering Defendants deny the remaining allegations of paragraph 37.

38. Answering Defendants say the allegation regarding duty is a conclusion of law requiring no response. To the extent a response is required, Answering Defendants say they performed all duties required by law. Answering Defendants deny the allegations of paragraph 38; and, are without information sufficient to form a belief as to the allegations regarding Indevus and, therefore, deny same.

39. Answering Defendants state that the writings referenced in paragraph 39 of the Complaint speak for themselves and any attempt to characterize them is denied. Answering Defendants deny each and every other allegation of paragraph 39 of the Complaint.

40. Answering Defendants state that the writings referenced in paragraph 40 of the Complaint speak for themselves and any attempt to characterize them is denied. Answering Defendants deny each and every other allegation of paragraph 40 of the Complaint.

41. Answering Defendants state that the writings referenced in paragraph 41 of the Complaint speak for themselves and any attempt to characterize them is denied. Answering Defendants deny each and every other allegation of paragraph 41 of the Complaint.

42. Answering Defendants state that the writings referenced in paragraph 42 of the Complaint speak for themselves and any attempt to characterize them is denied. Answering Defendants deny each and every other allegation of paragraph 42 of the Complaint.

43. Answering Defendants deny the allegations of paragraph 43.

44. Answering Defendants admit that representatives of AHPC met with representatives of the Mayo Clinic. Answering Defendants state that the writings referenced in paragraph 44 of the Complaint speak for themselves and any attempt to characterize them is denied. Answering Defendants deny each and every other allegation of paragraph 44 of the Complaint. With respect to Indevus, Answering Defendants are without knowledge sufficient to form a belief as to the truth of the allegations and, therefore, deny same.

45. Answering Defendants admit that representatives of AHPC met with representatives of the Mayo Cinc. Answering Defendants state that the writings referenced in paragraph 45 of the Complaint speak for themselves and any attempt to characterize them is

denied. Answering Defendants deny each and every other allegation of paragraph 45 of the Complaint.

46. Answering Defendants state that the writings referenced in paragraph 46 of the Complaint speak for themselves and any attempt to characterize them is denied. Answering Defendants deny each and every other allegation of paragraph 46 of the Complaint.

47. Answering Defendants deny the allegations of paragraph 47.

48. Answering Defendants deny the allegations of paragraph 48.

49. Answering Defendants state that the writings referenced in paragraph 49 of the Complaint speak for themselves and any attempt to characterize them is denied. Answering Defendants deny each and every other allegation of paragraph 49 of the Complaint.

50. In August 1997, a black box warning was incorporated. Answering Defendants state that the writings referenced in paragraph 50 of the Complaint speak for themselves and any attempt to characterize them is denied. Answering Defendants deny each and every other allegation of paragraph 50 of the Complaint.

51. Answering Defendants state that the writings referenced in paragraph 51 of the Complaint speak for themselves and any attempt to characterize them is denied. Answering Defendants deny each and every other allegation of paragraph 51 of the Complaint.

52. Answering Defendants admit that Pondimin and Redux were voluntarily withdrawn from the market on September 15, 1997. Answering Defendants state that the writings referenced in paragraph 52 of the Complaint speak for themselves and any attempt to characterize them is denied. Answering Defendants deny each and every other allegation of paragraph 52 of the Complaint.

53. Answering Defendants state that the writings referenced in paragraph 53 of the Complaint speak for themselves and any attempt to characterize them is denied. Answering Defendants deny each and every other allegation of paragraph 53 of the Complaint.

54. Answering Defendants admit that Pondimin and Redux have been approved by the FDA for mono-drug therapy. Answering Defendants deny each and every other allegation of paragraph 54 of the Complaint.

55. Answering Defendants deny each and every allegation of paragraph 55 of the Complaint.

56. Answering Defendants deny each and every allegation of paragraph 56 of the Complaint.

57. Answering Defendants deny each and every allegation of paragraph 57 of the Complaint.

58. Answering Defendants deny each and every allegation of paragraph 58 of the Complaint.

59. Answering Defendants deny each and every allegation of paragraph 59 of the Complaint.

60. Answering Defendants deny each and every allegation of paragraph 60 of the Complaint.

61. Answering Defendants deny each and every allegation of paragraph 61 of the Complaint.

62. Paragraph 62 of the Complaint contains legal conclusions to which no response is required of Answering Defendants, but if a response is required, Answering Defendants deny same. Answering Defendants deny each and every other allegation of paragraph 62.

63. Answering Defendants say that the allegations of paragraph 63 of the Complaint are a conclusion of law to which no response is required. To the extent a response is necessary, Answering Defendants deny the allegations of paragraph 63.

64. Answering Defendants deny each and every allegation of paragraph 64 of the Complaint. With respect to Indevus, Answering Defendants are without knowledge sufficient to form a belief as to the truth of the allegations and, therefore, deny same.

65. Answering Defendants deny each and every allegation of paragraph 65 of the Complaint. With respect to Indevus, Answering Defendants are without knowledge sufficient to form a belief as to the truth of the allegations and, therefore, deny same.

66. Answering Defendants deny each and every allegation of paragraph 66 of the Complaint. With respect to Indevus, Answering Defendants are without knowledge sufficient to form a belief as to the truth of the allegations and, therefore, deny same.

67. Answering Defendants deny each and every allegation of paragraph 67 of the Complaint.

**FIRST CAUSE OF ACTION**  
**(Strict Liability-Failure to Warn)**

68. Answering Defendants incorporate by reference all of the foregoing paragraphs of this Answer as if fully set forth here.

69. Answering Defendants deny each and every allegation of paragraph 69 of the Complaint. With respect to Indevus, Answering Defendants are without knowledge sufficient to form a belief as to the truth of the allegations and, therefore, deny same.

70. Answering Defendants deny each and every allegation of paragraph 70 of the Complaint. With respect to Indevus, Answering Defendants are without knowledge sufficient to form a belief as to the truth of the allegations and, therefore, deny same.

71. Answering Defendants deny each and every allegation of paragraph 71 of the Complaint.

**SECOND CAUSE OF ACTION**  
**(Negligence)**

72. Answering Defendants incorporate by reference all of the foregoing paragraphs of this Answer as if fully set forth here.

73. Paragraph 73 of the Complaint contains legal conclusions to which no response is required of Answering Defendants, but if a response is required, Answering Defendants admit to all duties imposed by law. Answering Defendants deny each and every other allegation of paragraph 73 of the Complaint. With respect to Indevus, Answering Defendants are without knowledge sufficient to form a belief as to the truth of the allegations and, therefore, deny same.

74. Answering Defendants deny each and every allegation of paragraph 74 of the Complaint. With respect to Indevus, Answering Defendants are without knowledge sufficient to form a belief as to the truth of the allegations and, therefore, deny same.

75. Answering Defendants deny each and every allegation of paragraph 75 of the Complaint. With respect to Indevus, Answering Defendants are without knowledge sufficient to form a belief as to the truth of the allegations and, therefore, deny same.

**THIRD CAUSE OF ACTION**  
**(Negligence Per Se)**

76. Answering Defendants incorporate by reference all of the foregoing paragraphs of this Answer as if fully set forth here.

77. Paragraph 77 of the Complaint contains legal conclusions to which no response is required of Answering Defendants, but if a response is required, Answering Defendants admit to all duties imposed by law. Answering Defendants deny each and every other allegation of paragraph 77. With respect to Indevus, Answering Defendants are without knowledge sufficient to form a belief as to the truth of the allegations and, therefore, deny same.

78. Answering Defendants deny each and every allegation of paragraph 78 of the Complaint. With respect to Indevus, Answering Defendants are without knowledge sufficient to form a belief as to the truth of the allegations and, therefore, deny same.

79. Paragraph 79 of the Complaint contains legal conclusions to which no response is required of Answering Defendants, but if a response is required, Answering Defendants admit to all duties imposed by law. Answering Defendants deny each and every other allegation of paragraph 79.

80. Answering Defendants deny each and every allegation of paragraph 80 of the Complaint, including subparts (a)-(j). With respect to Indevus, Answering Defendants are without knowledge sufficient to form a belief as to the truth of the allegations and, therefore, deny same.

81. Answering Defendants deny each and every allegation of paragraph 81 of the Complaint.

#### **FOURTH CAUSE OF ACTION** **(Breach of Implied Warrant)**

82. Answering Defendants incorporate by reference all of the foregoing paragraphs of this Answer as if fully set forth here.

83. Paragraph 83 of the Complaint contains legal conclusions to which no response is required of Answering Defendants, but if a response is required, Answering Defendants admit

that Pondimin and Redux were marketed for use in accordance with the FDA-approved prescribing information and subject to the precautions, warnings and contraindications stated therein, and that Answering Defendants gave such implied warranties as are imposed by law, if any. Answering Defendants deny each and every other allegation of paragraph 83 of the Complaint. With respect to Indevus, Answering Defendants are without knowledge sufficient to form a belief as to the truth of the allegations and, therefore, deny same.

84. Answering Defendants lack knowledge or information sufficient to form a belief as to what plaintiff relied upon and whether such reliance was reasonable. Answering Defendants deny each and every other allegation of paragraph 84 of the Complaint. With respect to Indevus, Answering Defendants are without knowledge sufficient to form a belief as to the truth of the allegations and, therefore, deny same.

85. Answering Defendants deny each and every allegation of paragraph 85 of the Complaint. With respect to Indevus, Answering Defendants are without knowledge sufficient to form a belief as to the truth of the allegations and, therefore, deny same.

86. Answering Defendants deny each and every allegation of paragraph 86 of the Complaint. With respect to Indevus, Answering Defendants are without knowledge sufficient to form a belief as to the truth of the allegations and, therefore, deny same.

**FIFTH CAUSE OF ACTION**  
**(Breach of Express Warranty)**

87. Answering Defendants incorporate by reference all of the foregoing paragraphs of this Answer as if fully set forth here.

88. Paragraph 88 of the Complaint contains legal conclusions to which no response is required of Answering Defendants, but if a response is required, Answering Defendants admit that Pondimin and Redux were marketed for use in accordance with FDA-approved prescribing

information and subject to the precautions, warnings and contraindications stated therein, and that Answering Defendants gave such implied warranties as are imposed by law, if any. Answering Defendants deny each and every other allegation of paragraph 88 of the Complaint. With respect to Indevus, Answering Defendants are without knowledge sufficient to form a belief as to the truth of the allegations and, therefore, deny same.

89. Answering Defendants lack knowledge or information sufficient to form a belief as to what plaintiff relied upon and whether such reliance was reasonable. Answering Defendants deny each and every other allegation of paragraph 89 of the Complaint. With respect to Indevus, Answering Defendants are without knowledge sufficient to form a belief as to the truth of the allegations and, therefore, deny same.

90. Answering Defendants deny each and every allegation of paragraph 90 of the Complaint. With respect to Indevus, Answering Defendants are without knowledge sufficient to form a belief as to the truth of the allegations and, therefore, deny same.

#### **SIXTH CAUSE OF ACTION** **(Negligent Misrepresentation)**

91. Answering Defendants incorporate by reference all of the foregoing paragraphs of this Answer as if fully set forth here.

92. Answering Defendants deny each and every allegation of paragraph 92 of the Complaint. With respect to Indevus, Answering Defendants are without knowledge sufficient to form a belief as to the truth of the allegations and, therefore, deny same.

93. Answering Defendants deny each and every allegation of paragraph 93 of the Complaint. With respect to Indevus, Answering Defendants are without knowledge sufficient to form a belief as to the truth of the allegations and, therefore, deny same.

94. Answering Defendants deny each and every allegation of paragraph 94 of the Complaint. With respect to Indevus, Answering Defendants are without knowledge sufficient to form a belief as to the truth of the allegations and, therefore, deny same.

95. Answering Defendants deny each and every allegation of paragraph 95 of the Complaint. With respect to Indevus, Answering Defendants are without knowledge sufficient to form a belief as to the truth of the allegations and, therefore, deny same.

96. Answering Defendants lack knowledge or information sufficient to form a belief as to what plaintiff relied upon. Answering Defendants deny each and every other allegation of paragraph 96 of the Complaint. With respect to Indevus, Answering Defendants are without knowledge sufficient to form a belief as to the truth of the allegations and, therefore, deny same.

97. Answering Defendants deny each and every allegation of paragraph 97 of the Complaint.

### **AFFIRMATIVE DEFENSES**

#### **First Affirmative Defense**

The Complaint fails to state a claim upon which relief can be granted.

#### **Second Affirmative Defense**

Plaintiff's causes of action are barred in whole or in part by the applicable statute of limitations, to the extent not otherwise provided in § IV.D.3.c, § IV.D.4.c, and/or § VII.B.4 of the Nationwide Settlement Agreement With American Home Products Corporation ("Settlement Agreement") approved by the United States District Court for the Eastern District of Pennsylvania.

**Third Affirmative Defense**

Plaintiff's causes of action are barred in whole or in part by the doctrine of laches, waiver and estoppel, to the extent not otherwise provided in § IV.D.3.c, § IV.D.4.c, and/or § VII.B.4 of the Settlement Agreement.

**Fourth Affirmative Defense**

Plaintiff's Complaint is defective in that Plaintiff has failed to join indispensable parties.

**Fifth Affirmative Defense**

Plaintiff's causes of action are barred in whole or in part by Plaintiff's comparative and/or contributory negligence.

**Sixth Affirmative Defense**

Plaintiff's damages, if any, were caused, solely or partially, or proximately caused by, some third person or third party for whom Answering Defendants are not legally responsible.

**Seventh Affirmative Defense**

Plaintiff's alleged damages resulted from new and independent, unforeseeable, superseding and/or intervening causes unrelated to any conduct of, or product placed in the stream of commerce by, Answering Defendants.

**Eighth Affirmative Defense**

Plaintiff's alleged damages were the result of pre-existing conditions unrelated to any conduct of, or product placed in the stream of commerce by, Answering Defendants.

**Ninth Affirmative Defense**

Plaintiff's alleged damages were the result of an idiosyncratic reaction, which Answering Defendants could not reasonably foresee.

**Tenth Affirmative Defense**

Plaintiff's damages, if any, and if they were caused by Pondimin or Redux, were caused in whole or in part by misuse or unintended use of the product.

**Eleventh Affirmative Defense**

Plaintiff's damages, if any, were caused by changes and/or alterations to Answering Defendants' products made by persons not within Answering Defendants' control.

**Twelfth Affirmative Defense**

Answering Defendants provided complete and adequate warnings to Plaintiff's prescribing physicians. Therefore, any claims by Plaintiff for inadequate warnings are controlled by, and barred under, the learned intermediary doctrine.

**Thirteenth Affirmative Defense**

Plaintiff's causes of action are barred in whole or in part by the lack of a defect, as the pharmaceuticals ingested by Plaintiff were properly prepared in accordance with the applicable standard of care.

**Fourteenth Affirmative Defense**

Plaintiff's product liability causes of action are barred because the benefits of Pondimin and/or Redux outweighed the risks.

**Fifteenth Affirmative Defense**

Plaintiff's product liability causes of action are barred because the relevant products were consistent with or exceeded consumer expectations.

**Sixteenth Affirmative Defense**

Based on the state of scientific, medical, and technological knowledge at the time Pondimin and/or Redux was marketed, the subject pharmaceuticals were reasonably safe for normal and foreseeable use at all relevant times.

**Seventeenth Affirmative Defense**

Plaintiff's claims are barred, in whole or in part, because Answering Defendants complied with all applicable state and federal statutes and with the requirements and regulations of the FDA.

**Eighteenth Affirmative Defense**

Plaintiff's claims under Massachusetts law are barred by the doctrine of federal preemption.

**Nineteenth Affirmative Defense**

Plaintiff's claims against Answering Defendants are barred under Section 402A, comment k of the Restatement (Second) of Torts and Section 6 et seq. of the Restatement (Third) of Torts: Products Liability.

**Twentieth Affirmative Defense**

Plaintiff's strict liability claims cannot be maintained against a prescription drug manufacturer.

**Twenty-First Affirmative Defense**

The damages recoverable by Plaintiff, if any, must be reduced by any amount of damages legally caused by Plaintiff's failure to mitigate such damages in whole or in part.

**Twenty-Second Affirmative Defense**

Answering Defendants expressly deny that any third party engaging in the acts alleged by Plaintiff were acting as an agent or servant, or at the instruction or within the control of, Answering Defendants. Therefore, to the extent that Plaintiff seeks to recover for the acts or omissions of such third parties, Plaintiff's claims are barred as a matter of law.

**Twenty-Third Affirmative Defense**

Each item of economic loss alleged in the Complaint was, or with reasonable certainty will be, replaced or indemnified, in whole or in part, from collateral sources.

**Twenty-Fourth Affirmative Defense**

Should Answering Defendants be held liable to Plaintiff, which liability is specifically denied, Answering Defendants would be entitled to a set-off for all sums of money received or available from or on behalf of any tortfeasors for the same injuries alleged in the Complaint.

**Twenty-Fifth Affirmative Defense**

Plaintiff has not suffered any physical injuries that were proximately caused by any act or omission by Answering Defendants, and it is more likely than not that Plaintiff will not contract any illness or injury from the alleged use of the products which are the subject of this action.

**Twenty-Sixth Affirmative Defense**

All acts or omissions by Answering Defendants were undertaken in good faith without malice or recklessness, and were fully justified and reasonable under the circumstances.

**Twenty-Seventh Affirmative Defense**

Plaintiff has failed to plead the claim of fraud with the requisite specificity required by law.

**Twenty-Eighth Affirmative Defense**

To the extent, if any, that punitive damages are not barred by the Settlement Agreement and are permitted under Massachusetts law, Plaintiff's punitive damages claims are barred by the Constitution of the United States and the Constitution of the Commonwealth of Massachusetts.

**Twenty-Ninth Affirmative Defense**

To the extent, if any, that punitive damages are not barred by the Settlement Agreement and are permitted under Massachusetts law, Plaintiff must prove a claim for punitive damages by

proffering clear and convincing evidence of willful and malicious or wanton, reckless conduct, or by proffering evidence of a willing or knowing violation by Answering Defendants of the Massachusetts Consumer Act, Mass. Gen. Laws ch. 93A, §9, under Massachusetts and/or federal law. No act or omission by Answering Defendants was malicious, willful, wanton, reckless, or grossly negligent or in willful or knowing violation of the Consumer Act; therefore any award of punitive damages is barred.

**Thirtieth Affirmative Defense**

To the extent, if any, that punitive damages are not barred by the Settlement Agreement and are permitted under Massachusetts law, punitive damages are unjust, discriminatory, unconstitutionally vague and/or overly broad, because there is no explicit standard by which they can be measured or determined.

**Thirty-First Affirmative Defense**

To the extent, if any, that punitive damages are not barred by the Settlement Agreement and are permitted under Massachusetts law, with respect to Plaintiff's demand for punitive damages, Answering Defendants specifically incorporates by reference all standards or limitations regarding the determination and enforceability of punitive damages awards which arose in the U.S. Supreme Court decisions of *BMW of North America v. Gore*, 116 U.S. 1589 (1996) and *State Farm Mutual Automobile Insurance Co. v. Campbell*, 538 U.S. 408, 123 S.Ct. 1513 (2003).

**Thirty-Second Affirmative Defense**

Plaintiff's claims are subject to dismissal or transfer on the basis of improper venue.

**Thirty-Third Affirmative Defense**

Plaintiff's eligibility to exercise an Intermediate and/or Back-End Opt-Out right and file an individual lawsuit against Answering Defendants is subject to challenge by Answering Defendants pursuant to Section IV.D.3.c of the Settlement Agreement. Answering Defendants reserve the right to challenge Plaintiff's eligibility if and when Answering Defendants discover that Plaintiff is not eligible to exercise such an Intermediate Opt-Out right.

**Thirty-Fourth Affirmative Defense**

Plaintiff's causes of action are barred because, at all relevant times, plaintiff was a knowledgeable purchaser who was aware of the alleged hazards of Redux and/or Pondimin and, therefore, Plaintiff expressly or impliedly assumed the risk of any alleged damages.

**Thirty-Fifth Affirmative Defense**

Plaintiff's causes of action are barred because a reasonable purchaser and/or consumer would have been aware of the alleged risks of Redux and/or Pondimin.

**Thirty-Sixth Affirmative Defense**

Plaintiff's recovery, if any, should be reduced by the comparative negligence, fault, responsibility or causation attributable to third parties, for whom Answering Defendants are not legally responsible.

**Thirty-Seventh Affirmative Defense**

Plaintiff's causes of action are barred because Plaintiff was not a foreseeable user of the product.

**Thirty-Eighth Affirmative Defense**

Plaintiff's causes of action are barred because Plaintiff's alleged damages were not caused by any failure to warn on the part of Answering Defendants.

**Thirty-Ninth Affirmative Defense**

Plaintiff's causes of action are barred in whole or in part by Plaintiff's failure to assert a safer design for Redux and/or Pondimin.

**Fortieth Affirmative Defense**

Plaintiff's causes of action are barred in whole or in part because Answering Defendants complied with all applicable statutes and with the requirements and regulations of the FDA.

**Forty-First Affirmative Defense**

Plaintiff's causes of action are barred because she did not reasonably rely on any alleged express or implied warranty.

**Forty-Second Affirmative Defense**

Plaintiff failed to notify Answering Defendants of any alleged breach of warranty within a reasonable time after she discovered or should have discovered any such alleged breach and is, therefore, barred from recovery for such claims.

**Forty-Third Affirmative Defense**

Plaintiff's causes of action are barred because Plaintiff suffered no physical injury from Redux and/or Pondimin.

**Forty-Fourth Affirmative Defense**

Plaintiff impermissibly seeks to impose liability on conduct protected from liability by the First Amendment to the United States Constitution.

**Forty-Fifth Affirmative Defense**

Plaintiff's claims for punitive damages are in contravention of Answering Defendants' rights under the Commerce Clause of Article I, Section 8 of the United States Constitution, the Contracts Clause of Article I, Section 10 of the United States Constitution, and the prohibition against ex post facto laws embodied in Article I, Section 10 of the United States Constitution.

**Forty-Sixth Affirmative Defense**

Plaintiff is not entitled to recover attorney's fees.

**Forty-Seventh Affirmative Defense**

Plaintiff is a member of a class which is subject to the provisions of a Nationwide Class Action Settlement Agreement with American Home Products Corporation, approved by the United States District Court for the Eastern District of Pennsylvania. By reason of that Settlement Agreement, plaintiff's causes of action are barred in whole or in part by the doctrines of merger, bar, collateral estoppel, res judicata, release, discharge, accord and satisfaction, and covenant not to sue and are barred by an injunction entered by that Court.

**Forty-Eighth Affirmative Defense**

Answering Defendants reserve the right to amend their Affirmative Defenses.

**WHEREFORE**, Answering Defendants pray for relief and judgment against plaintiff as follows:

- A. That plaintiff take nothing by reason of her Complaint.
- B. That Answering Defendants recover their fees, costs, and attorneys' fees incurred herein;
- C. For such further and other relief as the court deems proper.

DATED this 27th day of July, 2004.

s/s Janice W. Howe  
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Janice W. Howe BBO #242190  
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*Counsel for Defendants Wyeth, Inc.,  
Wyeth Pharmaceuticals, Inc., and  
Wyeth-Ayerst International, Inc.*

**CERTIFICATE OF SERVICE**

This is to certify that I have this day served the within and foregoing document upon all parties to the above-captioned action by depositing a copy of same in the United States Mail in a properly addressed envelope with sufficient postage affixed thereto to ensure delivery to attorneys of record, this 27th day of July, 2004.

s/s Janice W. Howe

Janice W. Howe

*Counsel for Defendants Wyeth, Inc.,  
Wyeth Pharmaceuticals, Inc., and  
Wyeth-Ayerst International, Inc.*